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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,228	10/12/2001	Lothar W. Kleiner	ARC 2427 N1	9517
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EXAMINER				
BROWN, COURTNEY A				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

09/976,228

**Applicant(s)**

KLEINER ET AL.

**Examiner**

COURTNEY A. BROWN

**Art Unit**

1616

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 17-20, 28-32, 35, 48 and 50-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-20, 28-32, 35, 48, and 50-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The examiner of your application in the USPTO has changed. Examiner Courtney Brown can be reached at 571-270-3284.

#### ***Acknowledgement of Receipt***

The new examiner of record acknowledges the receipt of Applicant's Amendment filed on July 27, 2007 in response to the Office Action dated April 27, 2007.

#### ***Status of the Claims***

As a result of the aforementioned Amendments, claims 24, 57, and 58 have been cancelled and claims 17,35, and 48 have been amended . Claims 17-20, 28-32, 35, 48, and 50-52, filed on July 27, 2007 are currently pending examination for patentability.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-20, 28-32, 35, 48, and 50-52 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Peery et al. in view of Edgren et al.

***Applicant's Invention***

The Applicant claims a method for processing rate controlling membranes comprising: a) providing a membrane made of polyurethanes or polyether blocked amides copolymers, b) holding at room temperature for 0.5 to 7 days, c) heating to from 30 to 5 °C below the melting temperature of the membrane, d) maintaining the heating for 1 to 250 hours prior to incorporating the membrane into an implantable controlled drug delivery device, and e) incorporating in an implantable drug delivery device. In particular, the temperature is about 45 to 80 °C, and is held at this temperature for 1 to 75 hours. Also, Claims 32 and 52 require the membrane be positioned in sealing relationship with an internal surface containing an imbibing device and a piston dividing the drug and imbibing device, wherein the membrane accommodates the imbibing device. Claim 35 is drawn to the annealed rate controlling membrane.

***Determination of the scope and the content of the prior art  
(MPEP 2141.01)***

Peery et al. teach the implantable drug delivery device (Figure 2) that is the same as the instant invention (Figure 4 of the instant specification). The device of Peery et al. further

comprises a membrane made up of either a polyurethane or polyether blocked amides copolymers (column 6, lines 43-61; and Claims 10 and 17).

***Ascertainment of the difference between the prior art and the claims  
(MPEP 2141.02)***

Peery et al. do not teach the process of annealing the membranes by heating to a predetermined temperature for a set amount of time, followed by cooling and incorporation into the implantable device. However, Edgren et al. teach an implantable (column 5, lines 6-8) device that is first coated with a subcoat followed by an overcoat (column 5, lines 16-18). The implantable device, as shown in Figure 6, comprises an inner compartment 24 comprising on one end an imbibing composition 26, and on the other end a beneficial drug 25; wherein, the compartment is coated with a semipermeable subcoat 22 with an opening, i.e. exit passageway 23, on the same side as the drug. Therefore, the device of Edgren et al. is similar to that of Peery et al. in that the semipermeable subcoating allows external fluid to pass to the inner compartment, where the imbibing composition swells and the beneficial drug is then released through the exit passageway at a controlled rate. Thus, the semipermeable subcoating of Edgren et al. would need to be similar to the semipermeable membrane 26 of Peery et al., as Shown in Figure 2, which allows external fluid to enter into the device thereby swelling an imbibing composition 20 and releasing a drug 18 through an exit passageway 36. Edgren et al. further teach the process of forming the subcoating and overcoating layers of the implantable device by annealing, wherein the coating forming composition is brought up to a preselected temperature (i.e. an annealing temperature), kept at the annealing temperature for a preselected amount of

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time, and finally cooling to room temperature (column 8, lines 3-11). Edgren et al. further teach that the annealing process results in an annealed subcoat that is permeable to the passage of fluid and maintains its physical and chemical integrity in a fluid environment of use (column 8, lines 28-31). Also, Edgren et al. teach the annealing temperature is about 20 to 75 °C, and the predetermined time for annealing is about 5 to 90 hours (column 8, lines 17-20).

***Finding of prima facie obviousness***

***Rationale and Motivation (MPEP 2142-2143)***

Therefore, it would have been prima facie obvious for one skilled in the art at the time of the invention to anneal the membranes of Peery et al. by heating to a predetermined temperature of about 20 to 75 °C for 5 to 90, cooling to room temperature, and then incorporating into the implantable device, as taught by Edgren et al. for the purpose of maintaining its physical and chemical integrity in a fluid environment of use.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

*Examiner's Response to Applicant's Remarks*

Applicant's arguments filed on July 27, 2007 have been fully considered but they are not persuasive. Applicant argues that Peery et al. do not teach a method for processing rate controlled membranes and rate controlled membranes as recited in claims 17-20, 28-32, 35, 48, and 50-52. Although this is true, the rejection is based on combinations of references and Peery et al. do teach the implantable drug delivery device of the instant application. The teaching of Peery et al. is analogous art and reasonably pertinent to the particular problem with which the applicant was concerned.

Applicant also argues that Edgren et al. do not disclose or teach a method of processing rate controlling membranes including the feature, "maintaining the membrane at the predetermined temperature for a period of time of from about 1 to 250 hours prior to incorporating the membrane into an implantable controlled drug delivery device." This is not persuasive because, Edgren et al., in column 8, lines 3-11, teach the annealing of a wall-forming coat which comprises a heat-treatment process wherein the coating forming-composition is brought up to a preselected/annealing temperature and then kept at the annealing temperature for a preselected period of time. Edgren et al. teach the annealing temperature is about 20 to 75 °C, and the predetermined time for annealing is about 5 to 90 hours (column 8, lines 17-20). By Applicant's own admission, there is no patentable distinction in pretreating the annealing process prior to or subsequent to the incorporation of the annealed membrane into the drug delivery device (see page 4, paragraph 14 of the instant specification). Therefore, the claims of the instant application are taught by Edgren et al.



Additionally, Applicant argues that Edgren et al. do not disclose or teach a rate controlling membrane for an implantable drug delivery device which is “characterized by being subjected to an elevated temperature of about 30° C to about 5° C below the melting temperature of the membrane for a predetermined period of about 1-250 hours prior to incorporation into the drug delivery device.” This is not persuasive because, Edgren et al. teaches a coating composition useful for manufacturing a drug delivery device possessing drug release rate controlling properties (column 2, lines 42-45). Additionally, it is routine optimization for one of ordinary skill in the art to adjust the annealing temperatures to optimize the desired results. In this case, depending on the copolymer used, the adjustment of the annealing temperature ranges are routine optimization. As previously stated, by Applicants' own admission, there is no patentable distinction in pretreating by an annealing process prior to or subsequent to the incorporation of the annealed membrane into the drug delivery device (see page 4, paragraph 14 of the instant specification). Therefore, these claims of the instant application are also taught by Edgren et al.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

None of the claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR Only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Courtney Brown, whose telephone number is 571-270-3284. The examiner can normally be reached on Monday-Friday from 8 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Courtney A. Brown

Patent Examiner  
Technology Center 1600  
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/SHELLEY A. DODSON/  
Primary Examiner, Art Unit 1616